

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
9 June 2005 (09.06.2005)

PCT

(10) International Publication Number
WO 2005/051349 A3

(51) International Patent Classification⁷: **A61K 9/20**,
9/28, 31/55, A61P 25/20

(21) International Application Number:
PCT/IB2004/003872

(22) International Filing Date:
24 November 2004 (24.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
964/CHE/2003 25 November 2003 (25.11.2003) IN
930/CHE/2004 17 September 2004 (17.09.2004) IN

(71) Applicant (for all designated States except US): AU-
ROBINDO PHARMA LTD. [IN/IN]; Plot No. 2
Maitrivihar, Ameerpet, Hyderabad 500038 (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ALURI, Phanin-**
drudu [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitriv-
ihar, Ameerpet, Hyderabad 500038 (IN). **BABU, Justin**
[IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar,
Ameerpet, Hyderabad 500038 (IN). **RAO, Shaik, Sriniv-**
asa [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitriv-
ihar, Ameerpet, Hyderabad 500038 (IN). **GOGIA, Ashish**
[IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar,
Ameerpet, Hyderabad 500038 (IN).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE,
SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
28 July 2005

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS OF MIRTAZAPINE

(57) Abstract: The present invention relates to pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts. More particularly, the present invention relates to solid unit dosage forms of anhydrous mirtazapine or its pharmaceutically acceptable salts suitable for oral administration. The present invention also relates to a process for the preparation of pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts.

WO 2005/051349 A3

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/IB2004/003872A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K9/28 A61K31/55 A61P25/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/26621 A (AKZO NOBEL N.V; DE NIJS, HENRIK) 19 April 2001 (2001-04-19)	1,3, 7-15, 21
Y	example 1	1,3, 7-15, 21
X	----- REMERON - PATIENT PACKAGE INSERT: 'Online! 1994, XP002329207 Retrieved from the Internet: URL: http://www.fda.gov/medwatch/SAFETY/2004/jun_PI/RemeronTabs_PI.pdf 'retrieved on 2005-05-24! * DESCRIPTION *	1,2,6, 16-20
Y		1,2,6, 16-20
Y	----- EP 1 209 159 A (SUMIKA FINE CHEMICALS CO., LTD; SUMITOMO CHEMICAL COMPANY, LIMITED) 29 May 2002 (2002-05-29) claims -----	1-21
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

24 May 2005

Date of mailing of the international search report

09/06/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Minas, S

INTERNATIONAL SEARCH REPORT

Intern. Appl. No.
PCT/IB2004/003872

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 225 174 A (SUMIKA FINE CHEMICALS CO., LTD) 24 July 2002 (2002-07-24) page 5, paragraph 33; claims; examples -----	1-21
X	EP 0 436 252 A (AKZO N.V) 10 July 1991 (1991-07-10) claims; example 2 -----	1
X	WO 01/58453 A (AKZO NOBEL N.V; RUIGT, GERARDUS, STEPHANUS, FRANCISCUS; VAN DEN BERG,) 16 August 2001 (2001-08-16) examples -----	1

INTERNATIONAL SEARCH REPORT

Internat Application No

PCT/IB2004/003872

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0126621	A	19-04-2001	AT 274899 T	15-09-2004
			AU 780379 B2	17-03-2005
			AU 1023201 A	23-04-2001
			BR 0014593 A	11-06-2002
			CA 2386547 A1	19-04-2001
			CN 1378452 A ,C	06-11-2002
			CZ 20021315 A3	17-07-2002
			DE 1223914 T1	18-09-2003
			DE 60013466 D1	07-10-2004
			DE 60013466 T2	20-01-2005
			WO 0126621 A2	19-04-2001
			EP 1223914 A2	24-07-2002
			ES 2194618 T1	01-12-2003
			HK 1046641 A1	08-04-2005
			HU 0203148 A2	28-01-2003
			JP 2003511403 T	25-03-2003
			MX PA02003519 A	20-08-2002
			NO 20021730 A	30-05-2002
			NZ 518165 A	26-03-2004
			PL 354584 A1	26-01-2004
			SK 6452002 A3	10-09-2002
			TR 200200978 T2	23-09-2002
			ZA 200202293 A	20-06-2003
EP 1209159	A	29-05-2002	AT 282616 T	15-12-2004
			AU 4030101 A	06-06-2002
			CA 2346195 A1	27-05-2002
			DE 60107189 D1	23-12-2004
			EP 1209159 A2	29-05-2002
			JP 2002220390 A	09-08-2002
			SI 1209159 T1	30-04-2005
EP 1225174	A	24-07-2002	US 2002065413 A1	30-05-2002
			AT 261966 T	15-04-2004
			AU 763502 B2	24-07-2003
			AU 7447100 A	04-06-2001
			CA 2370376 A1	31-05-2001
			DE 60009117 D1	22-04-2004
			DE 60009117 T2	21-10-2004
			DK 1225174 T3	05-07-2004
			EP 1225174 A1	24-07-2002
			AU 6019900 A	04-06-2001
			ES 2214318 T3	16-09-2004
			WO 0138329 A1	31-05-2001
			WO 0138330 A1	31-05-2001
			PT 1225174 T	31-05-2004
			US 2002103372 A1	01-08-2002
			US 2003130504 A1	10-07-2003
			US 2004138447 A1	15-07-2004
EP 0436252	A	10-07-1991	AT 93136 T	15-09-1993
			AU 634614 B2	25-02-1993
			AU 6839890 A	04-07-1991
			CA 2033418 A1	01-07-1991
			DE 69002822 D1	23-09-1993
			DE 69002822 T2	23-12-1993
			DK 436252 T3	27-12-1993
			EP 0436252 A1	10-07-1991

INTERNATIONAL SEARCH REPORT

 Intern al Application No
 PCT/IB2004/003872

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0436252 A		ES 2060001 T3	16-11-1994
		IE 904531 A1	03-07-1991
		JP 3051459 B2	12-06-2000
		JP 4210638 A	31-07-1992
		KR 156735 B1	16-11-1998
		NZ 236626 A	28-10-1992
		PT 96401 A ,B	15-10-1991
		US 5238688 A	24-08-1993
		ZA 9010452 A	30-10-1991
WO 0158453 A	16-08-2001	AU 780439 B2	24-03-2005
		AU 3024701 A	20-08-2001
		BR 0108261 A	05-03-2003
		CA 2396209 A1	16-08-2001
		CN 1395487 A	05-02-2003
		CZ 20022330 A3	13-11-2002
		WO 0158453 A1	16-08-2001
		EP 1257278 A1	20-11-2002
		HU 0204391 A2	28-05-2003
		JP 2003522147 T	22-07-2003
		NO 20023803 A	09-10-2002
		PL 356721 A1	28-06-2004
		SK 11442002 A3	04-02-2003
		US 2003022888 A1	30-01-2003
		ZA 200205238 A	29-09-2003